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| 10/648,844 | 08/25/2003 | Subramaniam C. Krishnan | 30909-1 | 3856 |
| 24256 7590 08/06/2008 DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202 | | | | |
| EXAMINER | | | | |
| MALAMUD, DEBORAH LESTIE | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3766 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/648,844

Applicant(s)

KRISHNAN, SUBRAMANIAM C.

Examiner

DEBORAH MALAMUD

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 21, 36 and 37 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 18, 21, 36 and 37 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 16 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/5/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. The Examiner acknowledges the amendments received 18 April 2008. Claims 1-17, 19-20 and 22-35 are cancelled; claims 18, 21 and 36-37 are pending.

Claim Objections

2. Claims 21 and 36 are objected to because of the following informalities: throughout the amended subject matter of these claims, the word "interartial" should be replaced by "interatrial," for example in line 10 of claim 21. Appropriate correction is required.

Response to Arguments

3. Applicant's arguments, see "Remarks," filed 18 April 2008, with respect to the rejection(s) of claim(s) 18, 21 and 36-37 under Svenson have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Eigler et al (U.S. 6,328,699).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 18, 21 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Eigler et al (U.S. 6,328,699). Regarding claims 18, 21 and 36, Eigler discloses (col. 3, lines 30-65; col. 4, lines 1-22; Figure 1) a system for accessing the left atrium "from the right atrium through the atrial septum separating the right and left atria. The flexible lead (10) and pressure transducer (15) will be anchored to the atrial septum." A "Brockenbrough catheter and needle are used to pierce the atrial septum for access to the left atrium." Figure 1 depicts the system, which includes "a Brockenbrough catheter (20) inside a peel-away sheath (22), with a flexible guidewire residing within the Brockenbrough catheter." With the access assembly (18) in place within the right atrium (30), "the Brockenbrough catheter is used to pierce the atrial septum (41) by extending the Brockenbrough needle (not shown) through the atrial septum into the left atrium (36). In the figures, the atrial septum has been pierced by the needle, the catheter advanced over the needle, and the needle withdrawn from the catheter leaving the catheter in place inside the left atrium." The system (col. 7, lines 65-67; col. 1-8) includes "one or more additional sensors (75) configured to monitor pressure at a location outside the left atrium, or a different physical parameter inside the left atrium or elsewhere. For each sensor, a sensor lead (77 and 80) conveys signals from the sensor to a monitoring unit (82) disposed inside the housing of the unit. It should also be noted that the sensor lead connecting the pressure transducer to the monitoring

apparatus might also be combined with or run parallel to another lead such as an electrical EKG sensor lead or a cardiac pacing lead, either of which might be placed in or near the left atrium.”

6. Further regarding claim 36, Eigler discloses (col. 3, lines 54-57) placement of the lead and sensor “with the aid of visualization techniques including standard fluoroscopy, cardiac ultrasound, or other appropriate visualization techniques used alone or in combination.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eigler et al (U.S. 6,328,699). Eigler discloses the claimed invention except for an interelectrode separation of between about 2 mm and about 4 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an interelectrode separation of this length, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Furthermore, Eigler discloses the claimed invention but does not disclose expressly the tapered end of a catheter. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the catheter tip shape as

taught by Eigler, with the tapered end as claimed, because the applicant has not disclosed the tapered end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the catheter tip shape as taught by Eigler, because it is used to pierce the interatrial septum for atrial placement as required by the claim. Therefore, it would have been an obvious matter of design choice to modify Eigler to obtain the invention as specified in the claim(s).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH MALAMUD whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766